REMARKS/ARGUMENTS

Objection to the Information Disclosure Statement:

The Examiner has refused to consider one of the references submitted in the Applicant's IDS of March 4, 2004. It is respectfully submitted that this reference was filed along the other references in the IDS, as evidenced by the stamped return post card (copy attached hereto as Attachment A), and was perhaps inadvertently misplaced somewhere in the PTO prior to reaching the file. Attached is another copy of the reference. It should be noted that this reference was also included in the IDS filed the very same day for sister patent application Serial No. 10/615,888 (Examiner F. Krass – co-signer of the instant office action).

Claim rejections under 35 U.S.C. §112:

The Examiner has rejected claims 2 and 4 under 37 C.F.R. §112, second paragraph. The Examiner contends that the claims are indefinite in that there is no indication in the claims or specification defining the percent calculation. The Examiner's attention is directed to the first sentence of Paragraph 008 of the specification, which states in part:

> As described in more detail in the following examples, d-limonene, and in particular highly purified d-limonene (i.e. at least 98.5% purity), has been shown to be effective in killing or inhibiting the growth of a number of gram-positive and gram- negative bacteria, ..."

In addition, Paragraph 009 states in its entirety the following:

> The d-limonene may be purified by known distillation techniques, such as that described in U.S. Pat. No. 6,420,435, which is incorporated herein by reference in its entirety.

Example 3 of U.S. Pat. No. 6,420,435 (copy attached) is directed to the purification of "food grade" limonene, which is about 97% pure, to an ultra purified limonene of about 98.5% purity. It is respectfully submitted that the specification is clear that the percentages are directed to the purity of limonene, wherein the extra 1.5% limonene oil comprises other unwanted terpenes and similar impurities. Those of ordinary skill in the art are well aware of the different "grades" of limonene, which reflect the purity of the product, from 70% "lemon-lime" grade used in many household cleaners, for example, to untreated/technical grade (about 95%) to food grade (about 97% pure). The Examiner's attention is directed to U.S. Pat. 3,023,144 to Greathouse et. al., col.

1, lines 57-62 (currently cited against the Applicant's claims, as discussed below), which discusses the purification of limonene.

It should also be noted that similar dependent claims directed to the purity of limonene were also present in sister Application Serial No. 10/615,588, without objection from the Examiner (Ex. F. Krass). In fact, in rejecting the dependent claims in that application in view of the prior art, it was evident that the Examiner clearly understood that the recited percentages described the purity of limonene. Moreover, in the current office action, the Examiner, in her rejection of claims 2 and 4 (discussed below), clearly appears to understand that the instant claims are directed to the purity of limonene.

In view of the foregoing comments, it is respectfully requested that this rejection be withdrawn.

Claim rejections under 35 U.S.C. §102(b):

The Examiner has rejected claims 1, 3, and 5 under 35 U.S.C. §102(b) as being anticipated by Greathouse, et al. (U.S. Pat. No. 3,023,144) and by Chastain, et al. (U.S. Pat. No. 5,153,229). For the following reasons, the Applicant respectfully traverses this rejection.

The Examiner argues that Greathouse et al. teaches biocidal compositions for topical application containing d-limonene. The Examiner contends that since this reference states that citrus oils have been reported to possess some antibacterial activity (col. 1, lines 45-46), and since limonene is a chief constituent of citrus oils , then d-limonene also "possesses marked and definite germicidal and fungicidal activity." (Examiner's Action, page 4). However, on the contrary, Greathouse et al. teaches that "d-limonene per se has been found to possess comparatively little germicidal activity." (col. 1, lines 62-63). Consequently, the invention in Greathouse et al. is directed to compositions comprising other compounds, such as cymene, which are disclosed as having antibacterial activity. These compositions may further include limonene, which Greathouse et al. states "may act as a solvent and penetrant" to bring about an enhanced or synergistic bacteriocidal or fungicidal activity (col. 2, lines 38-49).

Clearly, Greathouse et al. teaches that limonene is not an anti-bacterial compound. It therefore necessarily follows that Greathouse, et al. does not teach a "method for killing or inhibiting the growth of bacteria externally on the skin or within the nasal cavity of an animal" using d-limonene. Claim 1 has been amended to clarify that the formulation comprising a therapeutically effective amount of d-limonene is applied to the skin or nasal cavity for a time sufficient for said d-limonene to effectively eradicate or inhibit the growth of said bacteria.

Chastain et al. similarly teaches that limonene is "not bacteriocidal" (col. 1, lines 16-18). Chastain, et al. is directed to limonene that has been purposely oxidized to create oxidized terpene compounds that do have antibacterial activity. The Applicant's claimed invention, however, is directed to the use of limonene, and not the use of any oxidized derivatives of limonene (such as those listed in col. 2 line 60 – col. 3, line 1), as an antibacterial agent. In fact, the preferred formulation is an ultra-pure limonene of at least 98.5% purity, thus containing very few amounts of impurities. Chastain et al. is directed to the use of different terpenes, nothwithstanding the fact that the starting material for preparing these terpenes is limonene. In fact, Chastain et al., like Greathouse et al., clearly teaches away from the use of limonene as an antibacterial compound.

In view of the foregoing, it is respectfully submitted that claim 1 as amended is not anticipated by Greathouse et al. or Chastain et al.

Claim rejections under 35 U.S.C. §102(e):

The Examiner has also rejected claims 1, 3, and 5 under 35 U.S.C. §102(e) as being anticipated by Franklin (U.S. Pub. No. 2003/0180349). For the following reasons, the Applicant respectfully traverses this rejection.

In order for a claim to be rejected under 35 U.S.C. §102, the cited reference must disclose, either expressly or inherently, all the elements and limitations of the claim. *See Kalman v. Kimberly-Clark*, 218 U.S.P.Q. 781 (Fed. Cir. 1983). In addition, the cited reference must be an enabling disclosure. *Chester v Miller,* 15 U.S.P.Q.2d 1333, 1336, n. 2 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself, and thereby the public, in possession of the invention. *In re Donohue*, 226 U.S.P.Q. 619, 624 (Fed. Cir. 1985).

It is respectfully submitted that the Franklin reference is not an enabling disclosure for teaching that limonene is effective in killing or inhibiting the growth of bacteria externally on the skin or within the nasal cavity of an animal. Limonene is merely mentioned in a laundry list of terpenes deemed "to work" in the invention; however, there is no discussion with respect to how limonene is formulated or applied, other than the broad disclosure with respect to various pharmaceutical compositions in general. In fact, limonene is only listed three times when long lists of terpenes are disclosed (paragraphs 0087, 0127, and 0133). Notably, while the publication contains fifteen separate written examples, not a single example describes the use of limonene whatsoever. Moreover, none of the claims are directed to the specific use of limonene or formulations comprising limonene.

Claim rejections under 35 U.S.C. §103(a):

The Examiner has further rejected claims 2 and 4 as being unpatentable under 35 U.S.C. §103(a) over Greathouse et al. in view of Wolf. For the reasons discussed above with respect to the patentablity of claim 1, it is respectfully submitted that claims 2 and 4, which are dependent thereon, are also patentable.

Obvious Double Patenting:

Claims 1 and 2 were provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 17 of then copending sister application Serial No. 10/615,588. Application Serial No. 10/615,588 has been abandoned, thereby obviating this rejection.

Conclusion:

In view of the foregoing amendments and remarks, it is respectfully submitted that claim 1 as amended as well as claims 2-5 dependent thereon, are patentable in view of the cited art, and thus withdrawal of the Examiner's rejections is hereby requested.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 5, 2006.

Laura G. Barrow